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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,669	09/17/2003	Satoshi Omura	8012-1018-1	2478
466	7590	10/14/2005	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			PESELEV, ELLI	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/663,669

Applicant(s)

OMURA ET AL.

Examiner

Elli Peselev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-6, 23 and 26-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,23 and 26-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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The disclosure is objected to because of the following informalities: the section "Brief Description of the Drawings" is missing from the specification.

Appropriate correction is required.

Claims 1 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth in the Office Action of April 1, 2005.

Applicant's arguments filed September 8, 2005 have been fully considered but they are not persuasive.

Applicant contends that any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed. This argument has not been found persuasive. On page 3 of the specification it is stated that the claimed pseudoerythromycin derivatives have disappeared antibacterial activity and enhanced promoting action for differentiation-induction. Yet Kirst et al (U.S. Patent No. 5,106,961) disclose closely analogous pseudoerythromycin derivatives having antibacterial activity. Therefore, it is clear that even minor variations in structural formula can lead to major differences in the activity of the psudoerythromycins. However, the instant claims encompass compounds which posses major structural differences such as a compound wherein R1 and R2 are alkyls of 2 carbon atoms and a compound wherein R1 and R2 are alkyls of 20 carbon atoms. A person having ordinary skill in the art at the time the instant invention was made would not expect said compounds having such major structural differences to possess similar activities.

Claims 3-6 and 26-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what is meant by the term "ally" (claim 26).

Claims 3 and 27 are substantial duplicates.

Claims 4 and 28 are substantial duplicates.

Claims 5 and 29 are substantial duplicates.

Claims 6 and 30 are substantial duplicates.

Claims 1, 3, 4, 23, 26-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoeltje et al (U.S. Patent No. 5,418,224) or Gidda et al (U.S. Patent No. 4,920,102) or Kirst et al (U.S. Patent No. 5,106,961) for the reasons set forth in the Office Action of April 1, 2005.

Applicant's arguments filed September 8, 2005 have been fully considered but they are not persuasive.

Applicant contends that the claimed compounds possess properties which render its it unobvious. This argument has not been found persuasive since applicant has not presented any evidence showing that the reference's compounds do not possess the same properties as the claimed compounds.

Claims 1, 5, 6, 23, 26 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoeltje et al (U.S. Patent No. 5,418,224) for the reasons set forth in the Office Action of April 1, 2005.

Applicant has not presented any evidence that compounds disclosed by Hoeltje et al do not promote the differentiation-induction of monocytes to macrophages.

Applicant's arguments filed September 8, 2005 have been fully considered but they are not persuasive.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

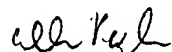
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

  
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GROUP 1200